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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,516	01/04/2002	Ashkan Imanzahral	31505.0001	6624

7590 03/13/2002

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/037,516	Applicant(s) IMANZAHRAL	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 4, 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6,8,10,12,14,16,18,20,22,24,26,28,31,34,36,38,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16,18,20 and 22* is/are allowed.

6)☒ Claim(s) *2, 4, 6, 8, 10, 12, 14, 24, 28, 31, 34, 36, 38, 41, 42* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The following is responsive to the preliminary amendment received Jan. 4, 2002.

Claims 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 30, 32, 33, 35, 37, 39 and 40 are cancelled. No new claims are added.

Claims 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 31, 34, 36, 38, 41, 42 are presented for prosecution on the merits.

Claim Objections

1. Claim 26 is objected to because of the following informalities: in claim 26, line 1, "according" should be deleted. Appropriate correction is required.

2. Claims 10, 12, 14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 10, 12, 14 all require that the amount of composition administered "reduce the migraine pain **and/or** "two or more, "three or more" and "all four" of the symptoms characteristic of a migraine. However, claim 2, at lines 1 and 9, sets forth a method for treating "migraine pain **and**" the symptoms characteristic of the migraine. Claims 10, 12, 14 fail to limit claim 2 because the terms **"and/or"** broaden the scope of claims 10, 12, 14. Applicant is respectfully requested to cancel the "/or".

PLEASE NOTE: if the claims are amended to delete the "/or", then claim 2 may be a substantial duplicate of claim 5.

Claim Rejections - 35 USC § 112

3. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 which depends from claim 34, provides for dosages forms "selected from the group consisting of tablets, pills, caplets, capsules and elixirs"; however, claim 34 requires the administration of "a liquid oral dosage form". Yet, "tablets, pills, caplets and capsules" are not in liquid form. Therefore, there is improper antecedent basis for "tablets, pills, caplets and capsules" in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 4, 6, 8, 10, 12, 14, 24, 28, 31, 34, 36, 38, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armellino et al., 5,972,916 in view of Munari et al. (as explained by Applicant's specification page 12, lines 9-23).

Armellino et al. teach a method and composition for treating migraine headaches and associated symptoms, i.e. nausea, phonophobia, photophobia, pain and functional disability, (see Applicant's claim 2, which recites "or functional disability") the method comprising administering an effective amount of a composition comprising acetaminophen, caffeine, aspirin and a pharmaceutically acceptable carrier such as a lubricants or disintegrants. The composition may be administered orally in tablet form or may administered in liquid form. The dosing interval is daily every four to six hours. Please see the abstract; col. 2-col. 3; col. 6, lines 3-56; col. 7, lines 30-33.

Armellino et al. do not disclose a method or composition for treating migraines and associated symptoms, i.e. functional disability, where the method administers a composition comprising acetaminophen and pseudoephedrine; however, the Examiner refers to the Munari et al. reference which discloses a study where pseudoephedrine was administered to migraine patients. The data demonstrated that pseudoephedrine was effective in treating "cardiovascular abnormalities", namely lower blood pressure and postural hypotension (see page 375 and 377; also, see Applicant's specification, page 12, lines 8-22; NOTE, page 376 is missing from the

Examiner's copy of the Munari et al. reference, **Applicant is respectfully requested to resubmit a complete copy of the Munari et al. article**).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Armellino et al. by combining pseudoephedrine with the acetaminophen-containing compositions of Armellino et al. because one of ordinary skill in the art would reasonably expect the additive effect of acetaminophen-containing compositions and pseudoephedrine to be effective in treating migraine pain and functional disability associated therewith. Moreover, one of ordinary skill in the art would reasonably expect pseudoephedrine to treat any cardiovascular abnormalities, i.e. a "functional disability", that the patients of Armellino may experience. Therefore, such a modification would have been motivated by the reasoned expectation of successfully and comprehensively treating a migraine and cardiovascular abnormalities associated therewith.

With respect to the claimed dosage amounts of pseudoephedrine, since Munari et al. establish that pseudoephedrine's efficacy is dependent upon dosage amounts, it would have been obvious to one of ordinary skill in the art to further modify the dosage amounts in the prior art such that pseudoephedrine is administered in an amount which is effective to optimize its effect in the treatment of cardiovascular abnormalities associated with migraines.

Finally, with respect to claim 42, since Armellino et al. establish a preferred dosing interval (col.7, lines 30-33), it would have been obvious to one of ordinary skill in the art to further

modify the dosing schedule such that the composition is effective in treating the patients suffering from migraines.

With respect to Armellino's use of aspirin and caffeine in the methods and composition, Applicant is reminded that the instant claims, recite "comprising" language which opens the claims and does not exclude other ingredients taught by the prior art but not claimed by Applicant. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App.1948)("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Please see MPEP 2111.03

Allowable Subject Matter

Claims 16, 18, 20, 22, and 26 are free from the prior art because the prior art does not disclose or fairly suggest the claimed methods and oral composition consisting of acetaminophen and pseudoephedrine.

Conclusion

Claims 2, 4, 6, 8, 10, 12, 14, 24, 28, 31, 34, 36, 38, 41, 42 are rejected.

Claim 26 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

March 7, 2002

Cybille Delacroix-Muirheid
Patent Examiner Group 1600